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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/980,133 | 02/22/2002 | Barry A. Morgan | 00537-190002 | 8080 |
| 7590 | 03/18/2004 | | EXAMINER | |
| Brian R Morrill Biomeasure Incorporated 27 Maple Street Milford, MA 01757 | | | | WAX, ROBERT A |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |
| DATE MAILED: 03/18/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/980,133 | MORGAN ET AL. | |
| | Examiner | Art Unit | |
| | Robert A. Wax | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-26 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>02142002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. The current application filed on February 22, 2002 is a 371 of PCT/US00/15396 filed on June 5, 2000, which in turn claims priority to provisional application, 60/137,655 filed on June 4, 1999.

Information Disclosure Statement

2. The information disclosure statement filed February 14, 2002 has been considered. Please see the attached initialed PTO-1449s.

Claim Objections

3. Claim 1 is objected to because of the following informalities: The definition of AA¹ includes the term "absentor" - obviously a space is missing; in the definition of AA² there is an extra comma between Cmp and Inc; and in the definition of AA⁶ there is an extra comma between Tic and Htic. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims read on peptides alleged to be agonists or antagonists of somatostatin; methods of eliciting a neuromedin B receptor agonist effect, methods of eliciting a somatostatin receptor agonist effect; methods of eliciting a SSTR-1 agonist effect and a method of treating one of 74 "diseases". The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because the specification gives no indication as to which of the many peptides within the scope of the structural formulae have agonistic activity for neuromedin B or somatostatin. Thus, practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to treatment of the 74 named conditions (obesity, for example, is not considered a "disease") since there is no guidance as to what treatment protocol to follow.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is very large because the number of peptides that fall within the structural formulae is very large; (2) the amount of guidance provided by the specification is zero since, although the methods of testing compounds for neuromedin B or somatostatin agonist activity are clearly set forth, there are no results of the tests set forth. One of skill in the art would have no idea what structural characteristics might make one peptide have agonist activity and another have antagonistic activity or no activity at all. Continuing, (3) the specification is totally

devoid of any working examples; the sentence at page 20, lines 6-8 is the closest the specification comes to showing actual examples, “[C]ompounds of the instant invention can be and were assessed for their ability to bind to a somatostatin subtype receptor according to the following assays.” The compounds may have been assessed but no results are presented.

As for the next Wands factor, (4) the nature of the invention is the delineation of a tremendous number of peptides possessing between six and ten amino acids. No structural relationship is shown for any of them and no comparison is shown with somatostatin or neuromedin B. The prior art (5) shows many somatotropin analogs, agonists and antagonists, including the anticipatory structure of Coy et al.; (6) the relative level of skill in this art is very high; (7) the predictability of the art of foretelling which compound will have agonistic activity is virtually zero. It is well known in the peptide art that even a small change in structure can have disproportionate effects on the function of the protein. Hemoglobin is the classic example of this – alteration of a single amino acid results in significant malfunction of the protein. Finally, (8) the claims are enormously broad. The first amino acid in the structural formula alone may be one of over 207 amino acids (one for absent, 140 for the D or L form of 70 choices, 66 for only some of the different substituents on one aromatic amino acid). Thus, the claims read on millions of different peptides.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Coy et al. (EP 0 395 417).

Coy et al. teach peptides corresponding to the instant structure wherein R¹ and R² are H, AA¹ is a substituted aromatic amino acid (Phe), AA² is Phe, AA³ is substituted Phe, AA^{3b} is D-Trp, AA⁴ is Lys, AA⁵ is Nle, AA⁶ is substituted Phe, AA⁷ is Nle, AA^{7b} is absent, AA⁸ is absent and R⁵ is absent (thus reading on Coy et al's R³ being H). These particular choices of amino acids represent one instance of anticipation by Coy et al. Other choices also anticipate claim 1.

Conclusion

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-

0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653